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June 24, 2021

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US
Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of the June 25, 2021 Discovery Hearing and Case Management Conference.

1. Status of Baohua Chen's Custodial File Production and Deposition Schedule

The Court ordered the production of the custodial file and denied the motion for protective order; thus, the deposition is to proceed. Accordingly, Plaintiffs requested an update from ZHP's counsel on the production and to ascertain potential dates for the deposition. On June 23, 2021, ZHP's counsel advised in an email: "The review is in progress and we are working toward the production deadline of July 12 set by the Court last week. We do not have dates to propose for Mr. Chen's deposition, as we are still evaluating the ruling Judge Vanaskie issued yesterday." In

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addition, during a June 23, 2021 meet and confer, Plaintiffs were advised by defense counsel that the collection of documents from Baohua Chen's computers and presumably the emails on the company's shared email platform prior to application of search terms is more than 20,000 documents. It is unclear to Plaintiffs why the search terms have not been applied yet so that we can be informed of the volume of documents.

Plaintiffs need to set dates for this deposition, based on schedules on both sides, and Plaintiffs request concrete information on Mr. Chen's documents, including the number identified with the search terms, and the extent to which any may be asserted as privileged or state secrets. This will allow the Parties and the Court to take into account potential briefing and decisions that may need to be made by the Court in order to finalize the production for the deposition, for purposes of scheduling of the deposition, which should go forward in August 2021.

2. Deficiencies with ZHP's Supplemental Production

The Parties continue to meet and confer regarding ZHP's supplemental production. ZHP confirmed to the Court at last week's conference that their supplemental production was substantially complete, but after reviewing the production, Plaintiffs believe there are significant deficiencies. Moreover, it is important for ZHP to define substantial completeness in the sense of advising what categories of documents they know will likely still be produced, as opposed to simply confirming that unknown responsive documents or information may become known to them at a later date.

In terms of deficiencies, the first major concern is that there are very few documents that have been produced for a number of custodians, including custodians that the Court ordered to be produced in Special Master Order No. 20. ([ECF 1233](#)). Though ZHP has indicated that their

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production was substantially complete, 21 of the custodians had less than 50 documents produced. Eight had less than 330 documents produced, and only two had more than 1,500 documents produced.

Of note, Jinsheng Lin, the author of the July 27, 2017 email in which he stated that there was NDMA in Valsartan, had only 205 documents produced. In fact, as further indication that Jinsheng Lin's custodial production is not complete – and/or that there are serious issues with responsive documents being withheld in violation of the Court's orders, the July 27, 2017 email was not even produced within Dr. Lin's custodial file. As the Court is already aware, Plaintiffs only learned about the email because a **copy** of the email was found in Dr. Lin's boss Min Li's custodial file (not the original electronic version) – with an incorrect date created in June 2018 indicated in the metadata. Nor was the email produced in the custodial files of any of the other recipients of the email, and nobody was named as a duplicate custodian. On top of this, no documents have been produced relative to how Dr. Lin knew there was NDMA in valsartan. ZHP shrugs these troubling facts off by claiming the email does not say what it says, and acting as if this is not a real issue, but objectively viewed, it appears that email was not meant to be produced (along with everything related) but slipped through due to the metadata error for the copy that was produced. In this connection, the report that was written as a result of that email, and which Min Li directed to be buried in April 2018 due to the “sensitive impurity” addressed in the report, cannot be located and thus has been destroyed. Based on this, all of ZHP's explanations for missing documents and information and facially inadequate productions are presumptively suspect.

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The document counts for the recently produced documents speak clearly to these issues:

Custodian	Documents Produced
Chen, Wenbin	1
Huang, Luning	1
Liu, Alex	1
Liu, Tina	1
Meng, Zheng	1
Tian, Sophie	1
Zhao, Xiaohong	1
Liu, Xiaoming	2
Ye, Jian	2
Huang, Tianpei	4
Li, Min	4
Wang, Dongqin	4
Zhou, Xiaohui	5
Tang, Fengyang	7
Ge, Jucai	8
An, Jianguao	14
Cai, Minda	15
Li, Qiangming	26
Li, Dan	27
Dong, Peng	34
Cheng, Wei	40
Xiong, Ying	64
Xu, Mi	96
Fang, Guojun	100
Zhong, Sheng	101
Li, Hongchao	167
Lin, Jinsheng	205
Liang, Zunjun	309
Zhou, Ting	323
Lin, Lihong	1,694
Wang, Wei	3,042
TOTAL	6,300

*Bolded custodians were ordered to be produced during the May 12, 2021 conference with Judge Vanaskie.

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ZHP admitted that these custodial productions were small and explained that in light of its “QC,” it would be producing 50 to 60 new documents next week. It is clear that as long as Plaintiff’s continue to focus on this issue, documents will likely continue to trickle in.

During the June 23, 2021 meet and confer, ZHP agreed to provide the custodians’ dates of employment, the dates when they received ZHP email addresses, and other pertinent employment information.

Another obvious issue is that almost all of the digital documents in the supplemental production post-date the recall or are attached to emails sent in or after June 2018. This is yet another red flag.

ZHP also informed Plaintiffs during the June 23, 2021 meet and confer that they have collected Maggie Kong’s documents and are taking the position that producing the documents will be overly burdensome. ZHP was unable or unwilling to answer questions intended to identify to what extent there were documents that clearly would not implicate privilege issues, for example scheduling emails, calendars (to show when meetings occurred, including those involving Baohua Chen), and other obviously not privileged documents. ZHP could not even give Plaintiffs any document or privilege counts to support their position and even admitted it would not have those counts until Monday. In other words, ZHP decided it will be asserting it cannot produce these documents despite not yet having the key facts to support that position. Plaintiffs object to any effort by ZHP to shield these documents from production.

There are also categories of documents that Plaintiffs have not been able to locate in the supplemental production that the Parties discussed.

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- 1. Documents related to TC-201729 (the Irbesartan improvement project discussed in the July 27, 2017 email) (see ZHP02636960).*
- 2. All copies, including drafts, of the report identified at tab 3, row 54 of ZHP01391683, wherein it indicates that “[a]fter discussion with Li, the project was not updated because the impurities involved were sensitive.”*
- 3. The November Deviation Investigation Report (PRINSTON0075797) says at page 35-36 that 7000 batches were tested after June 5, 2018. We do not see that volume of testing in the production—including references to a batch with 240ppm contamination. As such, Plaintiffs request the complete production of all batch testing records. To the extent you claim it has already been produced, please affirmatively identify the Bates ranges for such testing.*

With regard to the above categories, ZHP indicated that documents responsive to these requests were previously produced and indicated the production volume, but it declined to provide specific bates numbers for the responsive documents, with the exception of the bates numbers of the specific documents identifying the testing, which Plaintiffs need for their imminent expert reports. Plaintiffs have met and conferred with ZHP for over two months on this issue, and ZHP has repeatedly refused to cooperate and provide this information. ZHP attempted to focus the discussion on test results for USDMF valsartan (valsartan identified of the grade required for sale in the United States), which is not appropriate. This contradicts the Court’s macro discovery order, which required “defendants [to] produce all documents reflecting the presence of any nitrosamine in any sartan product.” ([ECF 303, ¶4](#)). In fact, the Court rejected ZHP’s effort to limit production to USDMF valsartan and required production of all testing of all valsartan manufactured in the facilities where the valsartan directed to the US was manufactured. The Court should order ZHP to produce all its testing for nitrosamines in its valsartan, regardless of whether it was USDMF. In

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addition, so that there is no question, ZHP should also definitively confirm the bates numbers for the testing of the batches used to manufacture the valsartan finished dose sold to Solco, and used to supply API to Torrent and Teva, who then manufactured finished dose for the purpose of sale in the United States. The Court should order this information to be provided by 5:00 p.m. eastern time on Friday, June 25, 2021. Otherwise, Plaintiffs will be significantly prejudiced in the preparation of their expert reports, which are due July 6, 2021. ([ECF 863](#)).

4. All records, including personnel files if necessary, associated with broken company issued cell phones and/or laptop computers for all custodians, including the date of occurrence and when and how the device was replaced, and location and status of the broken device.

This includes, but it not limited to:

a. Complete documentation associated with Min Li's broken Lenovo ThinkPad and Samsung Phone, including when the devices were rendered unusable, what steps were taken to retrieve information from the devices, what information was recovered from the devices and what information was destroyed, onto what device the recovered information was transferred and on which date the transfer occurred, and the location and status of the broken devices.

5. Plaintiffs also requested, "All records and documentation associated with Min Li's meeting with 'multi-national companies' where the decision was made by ZHP to limit its investigation of unknown peaks smaller than 20." Plaintiffs reviewed the additional documents produced in connection with Min Li's custodial file and have not been able to locate any documents responsive to this request.

ZHP agreed to produce additional documents responsive to these requests. The Court should order ZHP to produce these documents by 5:00 p.m. eastern time on Monday, June 28, 2021.

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3. Hetero's Privilege Log

As the Court is aware, the Plaintiffs challenged Hetero's privilege designations, and on May 17, 2021, Hetero de-designated documents that it previously asserted were privileged. The Plaintiffs have also requested the production of all documents similar to those that were de-designated pursuant to Judge Schneider's January 8, 2021 Order. Hetero agreed to review its designations and to de-designate additional documents based upon that review. The Parties have now met and conferred several times relating to these issues, most recently on June 22, 2021, but Hetero has not yet provided Plaintiffs with additional de-designations. At the June 22 meet and confer, Hetero stated that it will produce any additional documents that it de-designates by June 29, 2021 and to identify by bates number the identity of the de-designated documents produced, which were previously intermixed with newly produced documents. Plaintiffs believe that any remaining disputes as to the appropriateness of Hetero's privilege designations and its production of de-designated documents will be ripe and able to be addressed by the Court at the next discovery conference.

4. Defendants' In-Person Appearance at Plaintiffs' Depositions

Without meeting and conferring with the Plaintiffs' leadership, Defendants wish to raise their desire to attend Plaintiff's depositions in person. Aside from asserting this desire, Defendants have not explained the need to conduct these depositions in person.

Both sides spent many weeks negotiating a remote deposition protocol with this Court's help to provide for safety and security of witnesses, court reporters, and attorneys while maintaining rights of the parties involved. However, now that dozens of depositions have occurred and Defendant's fact witnesses depositions are substantially complete, Defendants claim a right to

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attend personal injury plaintiff's depositions in person. Specifically, they insist immune-compromised cancer patients travel to unfamiliar locations, spend hours with multiple strangers, and undergo the same questioning that has successfully been conducted remotely.

As we have an agreed upon protocol for conducting remote depositions, it should be clear that a person who is not comfortable should not be forced to attend depositions in person. This is true for individual plaintiffs, court reporters, videographers, and attorneys. Weighing the factors of safety is a highly personal determination and should remain a case-by-case determination, with the option to continue to use Zoom in whole or in part depending on the participants' comfort levels.

5. Treater Deposition Protocol

The Parties have met and conferred extensively regarding a deposition protocol for Bellwether treating physicians. While much progress has been made, three key issues remain unresolved:

First, Defendants will not agree to limit the number of treater depositions in any way. Rather, Defendants seek carte blanche to take depositions as they see fit for all 28 cases in the bellwether pool. In the *Benicar* MDL, the bellwether pool was winnowed *before* physician depositions. In that case, the Parties were limited to 1 prescriber and 1 treater deposition, and the parties alternated who led off questioning at the depositions. (*In re Benicar (Olmesartan) Products Liability Litigation CMO* 28). In this case, limiting the depositions in a similar manner makes sense. Should Defendants be allowed an unlimited number of depositions at this stage of the litigation, there will be many, many unnecessary depositions taken for cases that are eventually

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winnowed from the pool. This would be a colossal waste of time and expenses for all parties involved.

In addition, the Court previously indicated that it would readdress winnowing of the Bellwether pool at the June CMC, following the depositions of the first 10 bellwether cases:

Why don't we start out with the ten that you've got scheduled and then we'll revisit this matter in June once we have some groundwork done and we know where we're going with this because I find it hard to believe that we're not going to lose a lot of these plaintiffs when their depositions are scheduled or after they've been deposed. And I don't see really what the burden is of taking depositions of the providers and the prescribers of these ten plaintiffs, you know, in the meantime. So why don't we go ahead and do that. We will then re-examine this issue. We'll then make some decisions, if you don't, I will, as to how many we're going to winnow it down to and how we're going to proceed thereafter.

([3/31/21 CMC Tr. 86:14-25](#)). Plaintiffs can report that 9 of the 10 initial bellwether depositions have occurred, save for 1 plaintiff who contracted Covid but whose deposition if scheduled to occur shortly. Importantly, none of the bellwether plaintiffs have dismissed their cases and, again, Plaintiffs are aware of no cases where dismissal is forthcoming. Thus, Plaintiffs would alternatively suggest that the bellwether pool be winnowed at this time and then allow the Parties to discuss the scope of discovery on the remaining cases.

Second, the issue of costs associated with the treater depositions remains unresolved. Plaintiffs and Defendants have agreed to share in the costs of the first 2 depositions, but to the extent that Defendants are seeking an unlimited number of depositions, the cost of such depositions should be borne by the party seeking the additional depositions. Further, the Parties should share equally in the time for questioning the physicians regardless of which party schedules the deposition.

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Third, Defendants demand that Plaintiffs log all pre-deposition communications with treating physicians “other than communications regarding a plaintiff’s diagnosis, treatment or medical condition, or an inquiry regarding obtaining medical records or deposition scheduling.” Plaintiffs interpret this language to require the logging of an attorney’s pre-deposition communications with a physician. Defendants demand that such a log be provided to defense counsel within 48 hours of a physician’s deposition. Specifically, the log would require that Plaintiffs identify “when the communication occurred, the means (in person, telephone, email, etc.), its approximate duration, the participants, and *the identity of any documents or electronically stored information shown, provided to or otherwise described to the physician.*”

In essence, Defendants are demanding that a plaintiff’s counsel create a document for the purposes of this litigation in order for Defendants to learn what a plaintiff’s counsel did to prepare for a deposition, and, more importantly, what documents counsel felt may be relevant to her case. Plaintiffs object to this demand on the basis that the creation of a document by an attorney to provide an accounting of her actions during the pendency of litigation encroaches on the protections of the attorney-work product doctrine. The work-product protection shields from discovery “documents and tangible things that are *prepared in anticipation of litigation or for trial by or for another party or its representative,*” including its attorney. Fed. R. Civ. P. 26(b)(3)(A). It protects the attorney’s ability to “assemble information, sift what he considers to be the relevant from the irrelevant facts, prepare his legal theories and plan his strategy without undue and needless interference.” *Hickman v. Taylor*, 329 U.S. 495, 511 (1947). Certainly, Defendants are not prevented from asking at the deposition of a physician about his or her contact with plaintiff’s counsel, or even what documents, if any, were reviewed with plaintiff’s counsel.

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However, requiring plaintiff's counsel to create such a document for the purpose of revealing her actions, violates the work-product doctrine.

6. Plaintiff Fact Sheets/Show Cause Listings

Plaintiffs will be prepared to discuss this issue at the case management conference.

Respectfully,



ADAM M. SLATER